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October 19, 2001

Robert L. Stephenson, M.P.H., Director
Division of Workplace Programs, CSAP
Rockwall II, Suite 815
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Stephenson:

Below, please find our comments to the proposed revisions to the *Federal Register* June 9, 1994 (59 FR 29908) and September 30, 1997 (62 FR 51118) found in *Federal Register*/Vol. 66, No. 162/Tuesday, August 21, 2001 pages 43876-43882 (Department of Health and Human Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs):

Subpart A

Page	Section	Comment
43879	1.2	*Confirmatory Validity Test.* Definition does not include the need for the second test to have an analytical principle different from that used for the initial validity test. Please see p. 43882 16.(2).

Subpart B

Page	Section	Comment
43879	1.(2)	Will the definition of "amphetamines" remain as methamphetamine and amphetamine or be broadened to include methylenedioxyamphetamine, methylenedioxymethamphetamine, and/or methylendioxyethylamphetmaine?
43879	1.(3)	What laboratory qualifications are required?

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43880	4.(5)	Appears to be in conflict with *Federal Register*/Vol. 65, No. 244/Tuesday, December 19, 2000 pages 79462-79579 (Department of Transportation 49 CFR 40) 40.91(d), which states that unsuitable samples should be forwarded for further adulteration testing to another HHS-certified laboratory that has the capability of doing so. Clarification is needed on how to handle invalid results as either contacting the MRO or automatically sending to another HHS certified laboratory. Further clarification is required to identify the adulterant testing capability of each HHS-certified laboratory. If unsuitable samples are forwarded to another laboratory for additional adulteration testing, will feedback to the submitting laboratory for the results of such testing be allowed?
43880	4.(2)(ii)	For consistency, this should either be $\leq$3.0 or $\geq$11.0 or <3.0 or >11.0.
43880	4.(5)(v)	For consistency, this should either be $\leq$4.0 or $\geq$10.0 or <4.0 or >10.0.
43880	4.(k)(i)	For consistency, this should either be $\leq$3.0 or $\geq$11.0 or <3.0 or >11.0.
43881	10(d)	Of concern because it is not specified that the second test needs to employ an analytical methodology different from that used to perform the first test and, thus, may not be scientifically defensible. Please see p. 43882 16.(2).
43882	16.(2)	As stated above, not employing an analytical methodology in a second test different from the analytical methodology used in the first test may not be scientifically defensible.

Subpart C

No comments.

Please feel free to contact either author at 941.561.8208 (RMW) or 941.561.8251 (CEK).

Respectfully Submitted,

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Scientific Director/Responsible Person

Craig E. Knoblock, M.S.
Alternate Responsible Person

pc: Mr. Gotcher